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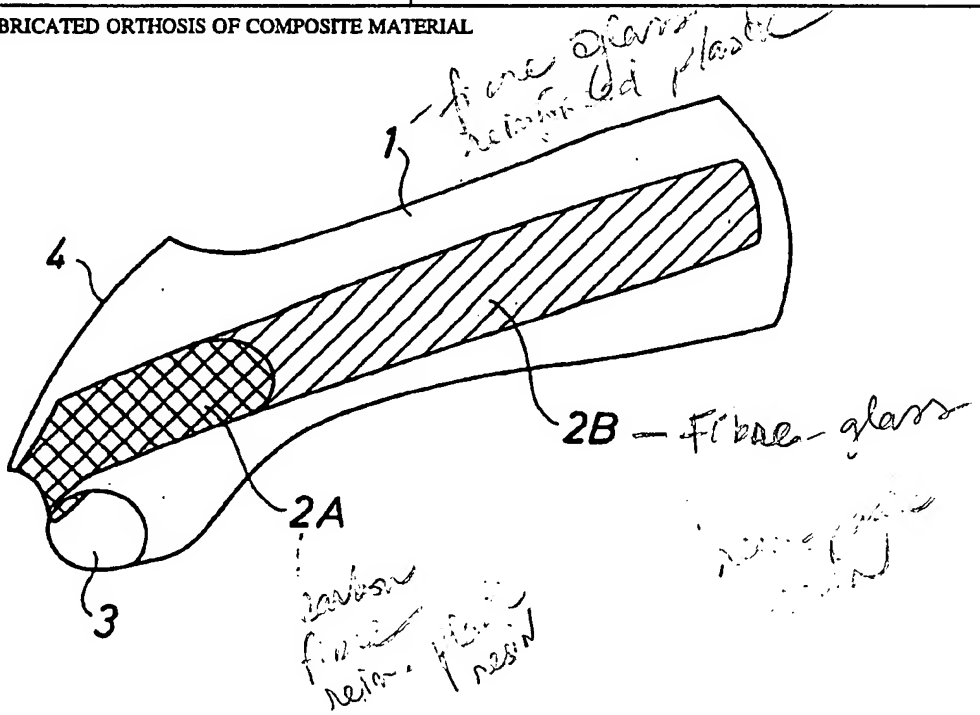

(57) Abstract

The present invention relates to a prefabricated orthosis consisting of a frame (1) of fibre-glass reinforced plastic resin and a reinforcement element (2A, 2B) of carbon and fibre-glass reinforced plastic resin. The frame (1) is sufficiently flexible to provide a good fit and the reinforcement element (2A, 2B) is sufficiently rigid to provide the required immobilisation. Due to the relative flexibility of the frame, the orthosis according to the invention has only to be manufactured in a few sizes to fit the majority of a grown-up population. The orthosis may be used e.g. as a wrist, ankle, elbow or knee joint orthosis.

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PREFABRICATED ORTHOSIS OF COMPOSITE MATERIAL

Technical area

The present invention relates to a prefabricated orthosis of composite material. The orthosis being prefabricated entails that it is not fitted individually, but is available in a few sizes that will fit most grown-up people. This is possible due to the use of a composite material which is partly is very flexible and partly very rigid. The material is also very thin and light-weight, which facilitates its use. The present invention may be applied to all kinds of orthoses, e.g. for the wrist, the ankle, the elbow and the knee joint.

State of the art

Orthoses have been manufactured from a variety of materials, of which plastic resins are today the most common ones. In order to make these materials strong enough, they have had to be made rather thick and are therefore also heavy to carry. Furthermore, the materials are of even thickness and of the same rigidity in all parts thereof. This entails that the orthosis will be partially unnecessarily thick and rigid, causing individual adaptation to be necessary in most cases. This adaptation is often complex and is made by way of a plaster mould of the extremity in question. The orthosis is then produced on this mould. Many of these orthoses also require special reinforcements of a different material, e.g. metal or plastic strips.

Another method of manufacturing orthoses is to form the orthosis directly on the patient. Examples of this method are plaster orthoses and some types of plastic resins.

The manufacture of these orthoses is thus time-consuming and demands a high occupational skill from the manufacturer.

Another problem with the orthoses having a uniform material thickness is the awkwardness of carrying them underneath garments and of taking them on and off. Further-

more, the patients are discomforted by the weight of the orthoses used.

The present invention solves the above problems by providing a prefabricated orthosis made of a composite material. The orthosis consists of a frame of fibre-glass reinforced plastic, thus being relatively flexible, and a component made of carbon fibre and fibre-glass reinforced plastic which is very strong and handles the supporting and immobilising functions. Due to the flexibility, only a few sizes are needed in order to still fit most grown-up people. Due to the carbon fibre and fibre-glass reinforcement, the orthosis is very strong but still thin and light.

Summary of the invention

The present invention thus provides a prefabricated orthosis comprising a frame of fibre-glass reinforced plastic and a reinforcement element made of carbon fibre and fibre-glass reinforced plastic, the frame having enough flexibility to provide a good fit and the reinforcement element being rigid enough to provide the required immobilisation. The fibre-glass reinforced plastic preferably consists of a number of layers of yarn fabric impregnated with an epoxy matrix, and the carbon fibre reinforced plastic consists of a number of layers of single direction carbon fibre fabric, impregnated with an epoxy matrix.

The invention is described in greater detail by the accompanying claims.

Brief description of drawings

The invention will now be described in detail with reference to the accompanying drawings, of which:

Fig. 1 is a perspective top view of a wrist orthosis for the right hand wrist, and

Fig. 2 is a perspective view from below of the orthosis of Fig. 1.

Detailed description of a preferred embodiment

The present invention will now be described with reference to a wrist orthosis, but the invention may of course be applied to any orthosis, e.g. for the ankle, the elbow and

the knee joint. A person can easily modify the described wrist orthosis for the application in question without any special equipment or specialist trade knowledge.

In order for a prefabricated orthosis to be useful, it must fulfil certain requirements. It must be flexible in certain areas, making the orthosis easy to take off and put on and making it suitable for extremities having different sizes, and furthermore requiring only a few sizes to fit the majority of the population. It must be rigid in other areas so as to give an adequate immobilisation of a wrist, a forearm, an ankle joint and of lower part of the lower extremities, etc. and it should furthermore have a low weight as well as a surface which is well tolerated both on the inside and the outside.

The figures depict a wrist orthosis from above and from below respectively. The orthosis comprises a frame 1 in which a reinforcement element 2A, 2B is embedded. There is a hole 3 for the thumb and an aperture 4 for the other fingers. The finished orthosis also has a padding along the edges to make it more comfortable to carry, and so called Velcro or hook-and-loop type mounting straps for fastening. The padding and the Velcro mountings are not shown, for increased clarity in illustrating the invention.

The frame is made from a thin yarn fabric of fibre-glass which is pre-impregnated with an epoxy matrix into a prepreg. A double layer is suitable for a wrist orthosis. For certain orthoses a smaller number of layers may be suitable at the edges of the orthosis to make it more flexible. Each finished layer has a thickness of at least about 0.2 mm.

Between the fibre-glass layers, the two-part reinforcement element is placed. Where the reinforcement element is to be strongest, it consists of a single-direction carbon fibre fabric impregnated with an epoxy matrix into a prepreg. For a wrist orthosis, this section is at the hand itself and is designated 2A in the figures. A number of layers as per requirement is used to obtain the suitable strength. The hardened carbon fibre material has a coefficient of elasticity comparable to that of steel. Each finished layer has a thickness of at least about 0.5 mm.

The remaining part of the reinforcement element, 2B, is

shaped from fibre-glass fabric which is also pre-impregnated with said epoxy matrix. For a wrist orthosis, a reinforcement element having two to four layers is suitable, extending dorsolaterally for a width of 30 - 40 mm.

The forming of the prepregs is made on a tool shaped in accordance with a cast of the wanted extremity part, in this case the lower part of the arm, of suitable size. The material is hardened in an oven in 120 ∞C for 120 minutes. After this, the material may be surface treated, e.g. be painted in any wanted colour, and the padding and the Velcro fasteners may be applied.

When using the orthosis, the frame 1 expands if the patient has thick arms whereas it can be pulled together by the Velcro fasteners if the patient has thin arms. At the same time, the reinforcement element 2A, 2B remains almost completely immobile.

The present invention thus provides a prefabricated orthosis having several advantages compared to the previously known technology; three sizes are expected to fit about 80% of the grown-up population, both male and female. The orthoses are easy to put on and take off by the patient himself. Due to their small sizes, they may be carried under garments, i.e. inside coat sleeves, trouser legs as well as shoes. They are easy to clean, and may thus be re-used by several patients. They are readily available at the surgeries for immediate use. They provide adequate inhibition of movement due to the reinforcement elements but still provide good mobility of fingers and toes. In case of a foot orthosis, shoes may be used and acceptable walking ability is provided.

The orthosis can be used for all soft part affections demanding a period of immobilisation, e.g. tendon inflammations, post-fracture conditions and joint damage where a further immobilisation is necessary. It may also be used for fissures without any misalignment and for more pronounced swelling. With suitable reinforcement, possibly by steel strips, the orthosis can also be used for acute fractures after repositioning.

As mentioned above, the invention is not limited to the embodiment described here. The invention is defined in the accompanying claims.

CLAIMS

1. Prefabricated orthosis, **characterized** by having a frame (1) made of fibre-glass reinforced plastic resin and a reinforcement element (2A, 2B) made of carbon and fibre-glass reinforced plastic resin, the frame (1) being sufficiently flexible to provide a good fit and the reinforcement element (2A, 2B) being sufficiently rigid for the required immobilisation.

2. Orthosis according to claim 1, **characterized** in that the fibre-glass reinforced plastic consists of a number of layers of yarn fabric impregnated with an epoxy matrix.

3. Orthosis according to claim 2, **characterized** in that each fibre-glass reinforced layer is $\geq$ 0.2 mm thick.

4. Orthosis according to any one of the preceding claims, **characterized** in that the carbon fibre-reinforced plastic consists of a number of layers of single-direction carbon fibre fabric impregnated with an epoxy matrix.

5. Orthosis according to claim 4, **characterized** in that each carbon fibre-reinforced layer is $\geq$ 0.5 mm thick.

6. Orthosis according to any one of the preceding claims, **characterized** in that the reinforcement element consists of a carbon fibre reinforced part (2A) and a fibre-glass reinforced part (2B).

7. Orthosis according to claims 5 or 6, **characterized** in that the reinforcement element (2A, 2B) is 30 - 40 mm wide.

8. Orthosis according to any one of claims 4 -7, **characterized** in that the number of fibre-glass reinforced layers is two and the number of carbon fibre reinforced layers is one to four.

9. Orthosis according to any one of the preceding claims, **characterized** in that the orthosis is a wrist, ankle, elbow or knee joint orthosis.

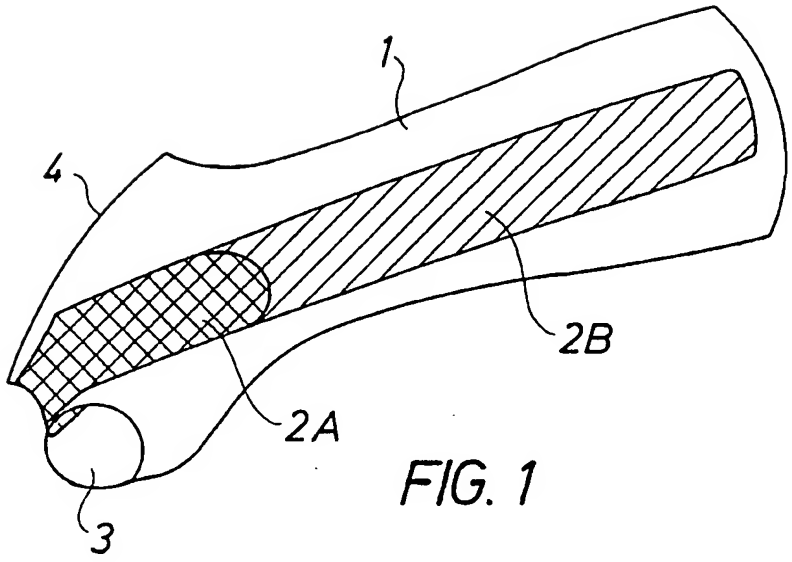

FIG. 1

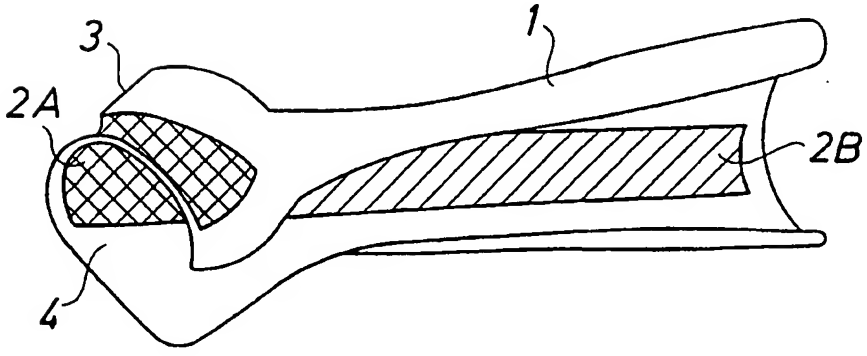

FIG. 2

INTERN..TIONAL SEARCH REPORT

International application No.
PCT/SE 95/00541

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 5/01
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, CLAIMS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4862900 A (W.J. HEFELE), 5 Sept 1989 (05.09.89), column 2, line 12 - line 15; column 3, line 50 - line 58, figure 2 --	1-9
Y	WO 9104721 A1 (TAMAGNI AG), 18 April 1991 (18.04.91), page 4, line 22 - line 26 --	1-9

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
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Date of the actual completion of the international search	Date of mailing of the international search report
7 Sept 1995	12 -09- 1995
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/SE 95/00541

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4862900	05/09/89	DE-A- 3640915	01/06/88
		EP-A,A,A 0269946	08/06/88
WO-A1- 9104721	18/04/91	AT-T- 111334	15/09/94
		AU-B- 631931	10/12/92
		AU-A- 6357390	28/04/91
		CH-A- 677601	14/06/91
		DE-D- 59007151	00/00/00
		EP-A,B- 0446308	18/09/91
		US-A- 5372572	13/12/94
		WO-A- 9104720	18/04/91